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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,880	03/25/2004	Banavara L. Mylari	PC23010B	9770

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
WEDDINGTON, KEVIN E	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,880	MYLARI, BANAVARA L.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 20-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 20-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3-25-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

Claims 1-9 and 20-28 are presented for examination.

Applicant's preliminary amendments filed March 25, 2004 and July 28, 2004; and the information disclosure statement filed March 25, 2004 have been received and entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Mylari et al., U.S. Patent No. 6,426,341 in view of Martin et al., U.S. Patent No. 6,730,674.

Claims 1-9 teach a pharmaceutical composition comprising a first compound selected from a compound from either formula I or formula II and a second compound that is a cyclooxygenase-2 inhibitor (COX-2). The Mylari et al. patent (6,426,341) teaches a pharmaceutical composition comprising an aldose reductase inhibitor (ARI) and a COX-2 inhibitor. The secondary reference, Martin et al. (6,730,674), teaches in

claim 1, may compounds within scope of current application claim 1 and the compounds are aldose reductase inhibitors. The claims in the Mylari et al. patent combined with the claims and teachings of Martin et al. patent would have made the current claims of the current application wherein the Martin et al. patent compounds (ARI) combined with Mylari et al. patent composition comprising an ARI and a COX-2 inhibitor showing the ARI are interchangeable. Thus the broad claims of the combined patent applications encompass the current application's more preferred aldose reductase inhibitors and COX-2 inhibitors.

Claims 1-9 are not allowed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of Mylari et al., U.S. Patent No. 6,413,965 in view of Martin et al., U.S. Patent 6,730,674.

Claims 1-9 teach a pharmaceutical composition comprising a first compound selected from a compound from either formula I or formula II and a second compound that is a cyclooxygenase-2 inhibitor (COX-2). The Mylari et al. patent (6,413,965) teaches a pharmaceutical composition comprising an aldose reductase inhibitor (ARI) and a COX-2 inhibitor wherein C0X-2 inhibitors are same as applicant's claims 5 and 24. The secondary reference, Martin et al. (6,730,674), teaches in claim 1, may compounds within scope of current application claim 1 and the compounds are aldose reductase inhibitors. The claims in the Mylari et al. patent combined with the claims and teachings of Martin et al. patent would have made the current claims of the current application wherein the Martin et al. patent compounds (ARI) combined with Mylari et al. patent composition comprising an ARI and a COX-2 inhibitor showing the ARI are interchangeable, and an obvious variation because it would have been obvious to combine compounds of Martin et al. patent in the composition(s) of the Mylari et al. patent in the absence of evidence to the contrary.

Claims 1-9 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 20-28are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not reasonably provide enablement for the prevention or treatment of cardiac tissue ischemia by the administering a pharmaceutical composition comprising a first compound selected from formulae I or II and a second compound that is a cyclooxygenase-2 inhibitor.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates a pharmaceutical composition and a therapeutic method comprising administering to a mammal in need of treatment or prevention of cardiac tissue ischemia with wherein the pharmaceutical composition is a first compound selected from formulae I or II and a second compound that is a cyclooxygenase-2 inhibitor.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

There are no known preventative therapies for cardiac tissue ischemia in the art.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusion drawn from laboratory data extrapolated to clinical efficacy.

The present invention is unpredictable unless experimentation is shown for pharmaceutical composition comprising a first compound selected from formulae I or II and a cyclooxygenase-2 inhibitor to treat cardiac tissue ischemia.

The breadth of the claims

The claims are very broad and inclusive to all aldose reductase inhibitors selected from formulae I or II disclosed in claims 1 and 20 combined with all cyclooxygenase-2 inhibitors.

The amount of direction or guidance provided and the presence or absence of working examples

There are no examples showing the instant pharmaceutical composition comprising a first compound selected from formulae I or II and a second compound that is a cyclooxygenase-2 inhibitor will, in fact, prevent cardiac tissue ischemia especially in a mammal not presently at risk of or predisposed to developing such a disorder.

There are no examples showing the combination of the first compound and the second compound into a single composition to treat cardiac tissue ischemia.

The working examples of the instant specification are limited to compounds derived from formula II to show that they are aldose reductase inhibitors.

The quantity of experimentation necessary

Applicant has failed to provide guidance as to which particular cause would be prevented for cardiac tissue ischemia. The skilled artisan would expect that interaction of a particular drug in the prevention of cardiac tissue ischemia to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis of the agent. The instant specification set forth no such understanding or any

criteria for extrapolating beyond the administration of instant pharmaceutical composition to treat cardiac tissue ischemia. Even for the data presented, no direction is provided to prevent cardiac tissue ischemia and its causes. Absent reasonable *a priori* expectations of success, one skilled in the art would have to test extensively many conditions that may lead to cardiac tissue ischemia to discover which cause is prevented. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as its is claimed in its current scope. The instant specification provides inadequate guidance to do otherwise.

Applicant has failed to provide guidance as to show the combination of the first compound selected from formulae I or II and a second compound that is a cyclooxygenase-2 inhibitor into a pharmaceutical composition is effective to treat cardiac tissue ischemia. The level of experimentation needed to determine the instant pharmaceutical composition would be able to treat cardiac tissue ischemia is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 1-9 and 20-28 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571) 272-0587. The examiner can normally be reached on 11:00 am-7: 30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
May 9, 2005